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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/488,500	01/20/2000	Klaus M. Irion	02581-P0204A	4514

7590 03/01/2002

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EXAMINER	
POTHIER, DENISE M	
ART UNIT	PAPER NUMBER
3764	

DATE MAILED: 03/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/488,500	IRION, KLAUS M.	
	Examiner	Art Unit	
	Denise M Pothier	3764	

-- Th MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in WIPO Office on 7-21-98. It is noted, however, that applicant has not filed a certified copy of the PCT application as required by 35 U.S.C. 119(b).

2. In addition, acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in WIPO on July 21, 1998. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application was filed more than twelve months thereafter.

Information Disclosure Statement

3. With specific regards to DE 3933159, DE 19731894, and DE 19529950, the information disclosure statement filed 1-20-00 fails to comply with 37 CFR 1.98(a)(3) because it does not include *a concise explanation of the relevance*, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, *of each patent listed that is not in the English language.* It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

4. Claims 1-43 are objected to because of the following informalities: the preamble "an endoscopic instrument" is inconsistent with the some of the depending claims, such

as claim 15, which includes additional elements. To overcome this objection, applicant should recite – an endoscopic system – in the preambles of claims 1-43. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 20, 22, 42, and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim s 20 and 42 recites the limitation "said observation element" in line 2. There is insufficient antecedent basis for this limitation in the claim. Note, the phrase, "through which an observation element can be introduced into a body" in claims 19 and 41 does not recite the observation element positively.

8. The remaining claims are rejected because they depend from a rejected claim.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1, 3-14, 19, 23, and 25-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iacovelli (5,350,391) in view of Gain (3,840,015). Iacovelli discloses in Figures 1-2 and in column 7, lines 15-32 that an endoscopic instrument comprising a shaft (12), a handle (20-22,24,26) arranged at a proximal end of the shaft and at least one marking (57) having a photo-luminescent substance (coating; col. 7, l. 30-32) that can be excited by a light source, the marking provided at a distal end section of the instrument, wherein the substance is selected in such as way that or is capable that its excitation range lies in an excitation range of a tumor-specific photosensitizer or of a tissue-autofluorscence. However, Iacovelli does not specifically disclose that the photo-luminescent coating is a fluorescing substance. Gain teaches in column 1, lines 10-40 and in column 2, lines 7-38 that it is known in the surgical instrument art to use a photo-luminescent material, including fluorescing substances, on forceps and other surgical instruments in order to improve visibility and to more clearly delineate the position and movement of the devices during surgery. Thus, one having ordinary skill in the surgical art would have known to make the photo-luminescent material of Iacovelli of a fluorescing substance in order to improve visibility and more accurate carry out the manipulative steps during surgery.

As for claims 3-4 and 25-26, see Figure 2 and column 7, lines 17-20 and 30-32 of Iacovelli disclosing the marking element is applied on the endoscopic instrument. As broadly as claimed, the coating is be applied removably by using a solvent to remove the coating.

As for claims 5-7 and 27-29, see Figure 2 and column 7, lines 15-32 disclosing the working elements (cutting blades) equipped with the markings in the distal end section of the shaft and are configured as two mouth parts.

As for claims 8 and 30 as broadly as recited, Iacovelli and Gain (col. 2, l. 58-59) disclose and teach a tubular shaft and the marking or coating is configured or capable of being a tubular bushing that can be slid onto the tubular shaft.

As for claims 9 and 31, Gain teaches in column 2, lines 33-42 that it is known to mix the fluorescing substance with a transparent material (polytetrafluroethylene) in order to provide a thin coating. Thus, one having ordinary skill in the art would have known to coat the fluorescing material with a transparent material in order to apply a thin coating to the instrument.

As for claims 10, 14, 32 and 36, see the above discussion and column 1, lines 16-50 of Iacovelli. The marking is capable or configured as a marking element to be inserted into the body during endoscopic procedures and anchored to the body during surgery.

As for claims 11 and 33, see column 2, lines 67-68 and column 3, line 1 (eosine, flourescein, rhodamine B or G) of Gain and the above teaching regarding using a fluorescing material.

As for claims 12-13 and 34-35, Iacovelli discloses in column 7 the use of multiple markings. Gain teaches and suggests in column 2, lines 2, lines 19-22 and 60-68 that the marking can be made of fluorescing substance of different materials or compounds

depending on the application. Thus, one skilled in the art would known to use different materials or excitable fluorescing substances depending on the application.

As for claims 13 and 35, Gain teaches in column 2, lines 60-64 that fluorescing material on the surgical instrument is selected for controlling the degree of toxicity and control. As such, Gain suggests that the markings can be made with differently concentrations in order to control the degree of toxicity. Also, Gain teaches in column 2, lines 19-22 and 60-68 that the fluorescing substance can be compound. As such, one skilled in the art would have known to make the marking a compound of various concentrations of the fluorescing substance of the markings in order to provide illumination around the surgical area.

As for claims 19 and 41, it is known during laproscopic procedures to use a manipulation device, like a trocar, in order to assist in inserting instruments into a body during surgery. Thus, one having ordinary skill in the art would have known to include a manipulation device during laproscopic surgery. In addition, Gain teaches that various surgical instruments, such as a manipulation device like the retractors and clamps, can include fluorescing materials. Thus, one having ordinary skill in the art would have known to include fluorescing material on various portions of the manipulation instrument, including an inner side of a manipulation instrument, in order to improve visibility.

As for claim 23, see the above discussion.

11. Claims 2 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iacovelli in view of Gain as applied to claims 1 and 23 above, and further in view of

Richards-Kortum (5,991,653). Neither Iacovelli nor Gain discloses the range in which the fluorescing substance on the instrument is excitable. Richards-Kortum discloses in column 3, lines 48-52 various fluorescent wavelength ranges, including 360-400 nm, for illuminate fluorescing substances. Thus, one having ordinary skill in the art would have known to select a fluorescing substance that is excited in the range of 370-440 nm or 400-500 nm in order to illuminate the fluorescing substance on a surgical instrument, such as that taught by Iacovelli and Gain.

12. Claims 12-13 and 34-35 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Iacovelli in view of Gain as applied to claims 1 and 23 above, and further in view of Sugai (6,099,537). Iacovelli and Gain disclose and teach the use of fluorescing substances that are differently excitable and in different concentrations. Sugai further teaches in column 12, line 62 – column 13, line 21 that it is known in the art to select different color combinations in order to improve the efficiency of manipulation. Thus, one having ordinary skill in the art would have known to make the markings taught by Iacovelli and Gain different excitable and to make the markings of different concentrations in order to improve manipulation during surgery.

13. Claims 15-18, 20-22, 37-39, and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iacovelli in view of Gain as applied to claims 1 and 23 above, and further in view of Nakamura (5,187,572). Iacovelli discloses using the device during laproscopic surgery. Gain teaches in column 3, lines 8-11 various light sources that can be used to excite the fluorescing material. As evidenced by Nakamura in Figures 33-35 and in columns 1-2, it is well known to use endoscopes, which include light-supplying

apparatus, connected to a light source (laser or lamp power) during different surgical procedures, such as laproscopic, in order to assist in visualization at different wavelengths depending on the observing part or purpose (col. 2, l. 6-10). Thus, one having ordinary skill in the art would have known to include a light-supplying apparatus and an endoscopic observation instrument with the Iacovelli instrument in order to assist in observing the laproscopic surgical field depending on the observing part or purpose.

As for claims 17 and 39, see Figure 1 and column 18, lines 38-54 of Nakamura teaching the inclusion of a camera in order to improve diagnostic ability. As such, one having ordinary skill in the art would have known to include a camera with the Iacovelli device in order to improve diagnostic ability.

As for claims 18 and 40, Nakamura teaches in Figures 4, 9, 14, 17 and 34 and in column 22, lines 10-35 that inclusion of an image processing system downstream from the camera capable of continuously detecting fluorescing markings in an endoscopic image in order to improve visualization and to visualize tissue.

As for claims 20 and 42, see the above discussion regarding a trocar and the teaching of Nakamura regarding using an endoscope to improve visibility.

As for claims 21 and 43, Nakamura teaches in column 4, lines 36-column 5, line 9 and the use of rotary disk in order to create intermittent or pulse light in order to adjust the quantity of illumination. Thus, it is known in the art to pulse light in order to adjust the quantity of illumination. Additionally, Nakamura teaches in column 4 synchronizing the light pulses with the pulses of the CCD driving circuit and memory controller. Thus, Nakamura teaches or suggests the light is pulsed at a frequency to correspond to the

frequency of the video imaging. Also, it is convention in the video and camera imaging art to operate the pulse frequency at least the frequency at which the image processing system operates in order to obtain good resolution. Thus, one having ordinary skill in the art would have known to pulse the light at a frequency which corresponds to a video image frequency of the endoscopic camera in order to display a good image of the fluorescing substance efficiently during surgery.

As for claim 22 and 44, see the above teaching of Gain including fluorescing and transparent material together on different surgical instruments and at the distal ends of the instruments (see Figs. 1, 3 and 5). Thus, one having ordinary skill in the art would have known to place transparent and fluorescing material at the distal end of the observation instrument in order to provide additional visibility during surgery.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Storz GMBH & Co. (WO 99/047719) discloses the state of the art of endoscopic instruments that include fluorescing material. Moriyama (5,810,715) discloses in column 13 the state of the art of endoscopes with fluorescing markings to improve visibility. Arenberg (5,419,312) discloses the state of the art of endoscopes that include a probe with a fluorescing coating.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Denise M. Pothier whose telephone number is

703.308.0993. The examiner can normally be reached on Monday-Thursday and alternate Fridays. The fax phone numbers for the organization where this application or proceeding is assigned are 703.872.9302 for regular communications and 703.872.9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Everett Williams whose telephone number is 703.305.1708.

Denise Pothier
Primary Examiner
February 21, 2002